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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,273	01/18/2005	Robert P Schnall	28657	7217

7590 04/07/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,273	SCHNALL, ROBERT P	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,8,11-16,18,20,21,23,33,34,37-41,44,47,49-52,57,58 and 62* is/are rejected.

7)☒ Claim(s) *5,7,9,17,19,22,24-32,35,36,42,43,45,46,48,53-56,59-61 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new grounds of rejection have been necessitated by the applicant's amendments to the claims.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the adhesive layer on the surface of the base facing the pressure applicator and sensor claimed in claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. See "Response to Arguments" below.

Claim Objections

Claims 24-32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 18, 20, 21, 33, 34, 38, 39, 50, 52, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,132,82 to Archibald et al. Regarding claim 1, 8, 18, and 50 Archibald discloses a probe for application to a selected area of a subject's skin covering a body part, which selected area serves as a measurement site for measuring changes in the pulsatile arterial blood volume thereat. The probe comprises a base 14, 22 for application to the selected area at said measurement site, a pressure applicator 148, 164, 168 carried by the base, and a

sensor 26A, B carried by the pressure applicator (see entire document, especially figs. 1, 3B; col. 3, lines 13-28; col. 4, lines 23-58; col. 5, lines 32-44 of Archibald).

The applicant discloses applying a static pressure of between venous pressure and diastolic pressure to the site as applying a static pressure of sufficient magnitude to partially unload the wall tension of but not to occlude the arteries at the measurement site, and applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to the measurement site through tissues surrounding the measurement site, thereby substantially preventing venous distention and blood pooling at the measurement site. The pressure applicator of Archibald is capable of applying any pressure to the skin at the measurement site, including a static pressure of the magnitude disclosed by the applicant as described above. The sensor of Archibald is capable of sensing changes in the pulsatile arterial blood volume, wherein pulsations sensed by the sensor are indicative of arterial volume changes (see entire document, especially col. 4, lines 51-58 of Archibald; also see applicant's disclosure of a piezoelectric elements as being such a sensor on p. 10, line 24-p. 11, line 11 of the instant specification).

The probe is configured to be applied to a relatively restricted area of the subject's skin to apply the static pressure to the relatively restricted area, which area does not completely encircle the body part at the measurement site. The pressure applicator occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site (see entire document, especially figs. 1, 3A, and 3B

of Archibald). The applicants should note that the language "to thereby permit free venous drainage from the measurement site via a wide region of unrestricted passageways surrounding the measurement site" is merely "results language" describing the results of the pressure applicator applying the static structure as described. This results language cannot be relied upon to define over the prior art, since Archibald. teaches all of the claimed structural features and their recited relationships. It is further noted that, since Archibald is configured to apply the static structure as claimed, if Archibald does not achieve the recited results, then the applicants have omitted an essential feature of the claimed invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph).

Regarding claim 8, the pressure applicator comprises a resilient elastomeric material for applying the static pressure to the measurement site (see entire document, especially figs. 3A, 3B; col. 5, line 32-col. 6, line 56 of Archibald).

Regarding claims 18, 20, 21, 33, 34, 38, 39, and 52 the apparatus of Archibald further comprises a data processor system for utilizing the measured changes to detect and indicate a medical condition or change in physiological state of the subject (see entire document, especially col. 4, line 23-col. 5, line 17; col. 8, lines 26-65 of Archibald) wherein the pulse waveform is indicative of arterial volume changes and therefore is a measure of such changes.

Regarding claim 20, such changes are used to indicate changes in the systemic blood pressure of the subject (see entire document, especially col. 4, line 23-col. 5, line 17; col. 8, lines 26-65 of Archibald).

Regarding claim 21, the processor system utilizes the measured changes to indicate the pulse rate (see entire document, especially col. 5, line 7-12; col. 8, line 65-col. 9, line 24 of Archibald).

Regarding claims 34 and 38, the probe is applied to a relatively restricted area of the subject's skin substantially overlying a medium to large sized artery (see entire document, especially fig. 1; col. 2, lines 42-47 of Archibald). With further regard to claims 38 and 39, the area is on a limb, and further on a wrist of the subject.

Regarding claim 50, a multiplicity of different sensors 26A, B are used for sensing changes in the pulsatile arterial blood volume at the measurement site (see entire document, especially fig. 3B; col. 4, lines 51-col. 5, line 7; col. 8, lines 26-65 of Archibald).

Regarding claim 52, the probe is applied over a skin region overlying a superficial conducting artery for deriving a signal (see entire document, especially fig. 1; col. 2, lines 43-47; col. 4, line 65-col. 5, line 17 of Archibald). As to the language "for biofeedback input", the applicant should note that this is merely "intended use" language describing the intended use of the derived signal, which language cannot be relied upon to define over the prior art, since Archibald teaches all of the claimed steps and their recited relationships. The signal derived from the probe could most certainly be used "for biofeedback input" as claimed.

Regarding claim 62, the pressure applied by the pressure applicator extends in area beyond the region of the sensor 26A, B to extend the effective boundary of the pressure field overlying the sensing region (see entire document, especially fig. 1; col.

4, lines 51-58; col. 5, lines 32-44 of Archibald), such that venous distention and blood pooling are substantially prevented at the measurement site and the underlying veins are effectively collapsed to limit the local venous blood flow while permitting free venous drainage with respect to the measurement site through surrounding tissues.

Claims 1, 3, 4, 10, 18, 20, 21, 33, 38, 50, 52, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,368,039 to Moses. Moses discloses a probe for application to a selected are of a subject's skin covering a body part, which area serves as a measurement site for measuring changes in the pulsatile arterial blood volume thereat. The probe comprises a base 12b for application to the selected area, a pressure applicator 10 carried by the base for applying a static pressure to the skin at the measurement site when the base is applied thereto, and a sensor 12c carried by the pressure applicator 12b for sensing changes in the pulsatile arterial blood volume at the measurement site when the base is applied to thereto (see entire document, especially figs. 2, 3a; col. 7, lines 38-61 of Moses). The pressure applicator 10 is designed to apply to the measurement site, when the base is applied thereto, a static pressure of a sufficient magnitude to partially unload the wall tension of, but not to occlude, the arteries at said measurement site and configured to substantially prevent venous distention and blood pooling at the measurement site by applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to the measurement site through tissues surrounding the

measurement site (see figs. 2, 3a; col. 10, lines 28-31 of Moses), wherein the applicants disclose such a static pressure as being a pressure above the local venous pressure and below the diastolic blood pressure (see claim 3, lines 1-16 of p. 4, lines 9-18 of p. 14 of the instant specification). The probe is configured to be applied to a relatively restricted area of the skin to apply the static pressure to the relatively restricted area, which area does not completely encircle the body part at the measurement site, and the pressure applicator occupies a relatively small fraction of the surface perimeter of the body part (see entire document, especially figs. 2, 3a; col. 10, lines 28-31 of Moses).

The applicants should note that the language "to thereby permit free venous drainage from the measurement site via a wide region of unrestricted passageways surrounding the measurement site" is merely "results language" describing the results of the pressure applicator applying the static structure as described. This results language cannot be relied upon to define over the prior art, since Moses teaches all of the claimed structural features and their recited relationships. It is further noted that, since Moses is configured to apply the static structure as claimed, if Moses does not achieve the recited results, then the applicants have omitted an essential feature of the claimed invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph).

Regarding claim 3, the pressure applicator 10 applies to the measurement site a static pressure above the subject's venous pressure and slightly below the diastolic pressure (see entire document, especially col. 13, lines 52-67of Moses).

Regarding claim 4, the pressure applicator comprises a fluid chamber and an external source of fluid for applying the static pressure (see entire document, especially fig. 2; col. 7, lines 38-48; col. 8, lines 10-18 of Moses).

Regarding claim 10, the base 12b includes a relatively non-stretchable material and carries the pressure applicator and sensor at the center thereof (see entire document, especially figs. 2, 3a; col. 10, lines 4-15 of Moses).

Regarding claim 18, 20, 21, 33, and 38, the apparatus disclosed by Moses further comprises a data processor system for utilizing the measured changes to detect and indicate a medical condition or change in physiological state of the subject (see entire document, especially col. 7, line 53-col. 8, line 65; col. 13, line 51-col. 14, line 22 of Moses), wherein changes in systemic blood pressure and the pulse rate are indicated (see entire document, especially col. 8, line 55-col. 9, line 5 of Moses).

With further regard to claim 38, the probe is applied to a relatively restricted area of the subject's skin on a limb of the subject (see entire document, especially fig. 2; col. 7, lines 38-43 of Moses).

Regarding claim 50, a multiplicity of different sensors is used for sensing changes in the pulsatile arterial blood volume at the measurement site (see entire document, especially fig. 3a; col. 7, lines 49-61 of Moses).

Regarding claim 52, the probe is applied over a skin region overlying a superficial conducting artery for deriving a signal (see entire document, especially fig. 2; col. 7, lines 38-45 of Moses). As to the language "for biofeedback input", the applicant should note that this is merely "intended use" language describing the intended use of the

derived signal, which language cannot be relied upon to define over the prior art, since Moses teaches all of the claimed steps and their recited relationships. The signal derived from the probe could most certainly be used "for biofeedback input" as claimed.

Regarding claim 62, the pressure applied by the pressure applicator extends in area beyond the region of the sensor 12c to extend the effective boundary of the pressure field overlying the sensing region (see entire document, especially figs. 2, 3a of Moses), such that venous distention and blood pooling are substantially prevented at the measurement site and the underlying veins are effectively collapsed to limit the local venous blood flow while permitting free venous drainage with respect to the measurement site through surrounding tissues.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 10, 18, 20, 21, 33, 38, 44, 50, 52, 57, 58, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable US Patent No. 6,332,869 to Ogura et al. in view of Moses. Ogura discloses providing multiple blood pressure measuring devices, each provided at its own measurement site for measuring the pulsatile arterial blood volume thereat, wherein the measurement from each probe is utilized for

detecting and indicating a medical condition or physiological state of the subject (see entire document, especially fig. 1; abstract; col. 1, lines 14-61; col. 5, lines 41-62 of Ogura). However, Ogura lacks at least one of the probes being the probe as disclosed in claim 1. The rejection of claim 1 as being anticipated by Moses, set forth above, describes how Moses teaches the probe of claim 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the blood pressure measuring device of Moses as that of Ogura, as it would merely be the substitution of one known blood pressure measuring device for another.

Regarding claim 3, the pressure applicator 10 applies to the measurement site a static pressure above the subject's venous pressure and slightly below the diastolic pressure (see entire document, especially col. 13, lines 52-67of Moses).

Regarding claim 4, the pressure applicator comprises a fluid chamber and an external source of fluid for applying the static pressure (see entire document, especially fig. 2; col. 7, lines 38-48; col. 8, lines 10-18 of Moses).

Regarding claim 10, the base 12b includes a relatively non-stretchable material and carries the pressure applicator and sensor at the center thereof (see entire document, especially figs. 2, 3a; col. 10, lines 4-15 of Moses).

Regarding claim 18, 20, 21, 33, and 38, the apparatus disclosed by Moses further comprises a data processor system for utilizing the measured changes to detect and indicate a medical condition or change in physiological state of the subject (see entire document, especially col. 7, line 53-col. 8, line 65; col. 13, line 51-col. 14, line 22

of Moses), wherein changes in systemic blood pressure and the pulse rate are indicated (see entire document, especially col. 8, line 55-col. 9, line 5 of Moses).

With further regard to claim 38, the probe is applied to a relatively restricted area of the subject's skin on a limb of the subject (see entire document, especially fig. 2; col. 7, lines 38-43 of Moses).

Regarding claims 50 and 57, a multiplicity of different sensors are used for sensing changes in the pulsatile arterial blood volume at the measurement site (see entire document, especially fig. 3a; col. 7, lines 49-61 of Moses).

Regarding claims 52 and 58, the probe is applied over a skin region overlying a superficial conducting artery for deriving a signal (see entire document, especially fig. 2; col. 7, lines 38-45 of Moses; col. 5, line 40-col. 9, line 52 of Ogura). As to the language "for biofeedback input", the applicant should note that this is merely "intended use" language describing the intended use of the derived signal, which language cannot be relied upon to define over the prior art, since Ogura teaches all of the claimed steps and their recited relationships. The signal derived from the probe could most certainly be used "for biofeedback input" as claimed.

Regarding claim 62, the pressure applied by the pressure applicator extends in area beyond the region of the sensor 12c to extend the effective boundary of the pressure field overlying the sensing region (see entire document, especially figs. 2, 3a of Moses), such that venous distention and blood pooling are substantially prevented at the measurement site and the underlying veins are effectively collapsed to limit the local

venous blood flow while permitting free venous drainage with respect to the measurement site through surrounding tissues.

Claims 1, 4, 6, 8, 10, 11, 18, 20, 33, 37, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,230,342 to Bobo, Jr. et al. in view of US Patent No. 4,896,676 to Sasaki et al. Bobo, Jr. teaches a probe for application to a selected area of a subject's skin covering a body part, which area serves as a measurement site for measuring changes in the pulsatile arterial blood volume thereat. The probe comprises a base 19, 20 for application to the selected area, a pressure applicator 18 carried by the base for applying a static pressure to the subject's skin at the measurement site when the base is applied thereto, and a sensor for sensing changes in the pulsatile arterial blood volume at the measurement site when the base is applied thereto (see entire document, especially figs. 1-3; col. 3, line 54-col. 4, line 31 of Bobo, Jr.) The applicants disclose applying a static pressure of between venous pressure and diastolic pressure to the site as applying a static pressure of sufficient magnitude to partially unload the wall tension of but not to occlude the arteries at the measurement site, and applying sufficient external counter pressure to effectively collapse the underlying veins and limit the local venous blood flow to the arterial throughput while permitting free venous drainage with respect to the measurement site through tissues surrounding the measurement site, thereby substantially preventing venous distention and blood pooling at the measurement site. The pressure applicator is capable of applying such a static pressure (see entire document, especially col. 4,

lines 9-30 of Bobo, Jr.) The pressure applicator is also configured to apply the static pressure to a relatively restricted area of the subject's skin, which area does not completely encircle the body part at the measurement site and occupies a relatively small fraction of the surface perimeter of the respective body part at the measurement site (see entire document, especially fig. 3 of Bobo, Jr.) The applicants should note that the language "to thereby permit free venous drainage from the measurement site via a wide region of unrestricted passageways surrounding the measurement site" is merely "results language" describing the results of the pressure applicator applying the static structure as described. This results language cannot be relied upon to define over the prior art, since Bobo, Jr. teaches all of the claimed structural features and their recited relationships. It is further noted that, since Bobo, Jr. is configured to apply the static structure as claimed, if Bobo, Jr. does not achieve the recited results, then the applicants have omitted an essential feature of the claimed invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph). Bobo, Jr. lacks the sensor being carried by the pressure applicator.

However, Sasaki teaches a probe having a pressure applicator and a sensor, wherein the sensor 14A is carried by the pressure applicator (see entire document, especially fig. 2; col. 3, lines 12-47 of Sasaki). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have the pressure applicator of Bobo, Jr. carry the sensor, as shown in Sasaki, as it would merely be the substitution of one known sensor and applicator configuration for another, wherein the location of the

sensor does not affect operation of the invention as a whole, and the combination would merely produce the predictable result of allowing a blood pressure measurement.

The applicant should note that the language "for applying a static pressure" on lines 6-7 of claim 1 and "designed to apply to said measurement site, when the base is applied thereto, a static pressure . . ." on lines 11-18 of claim 1, is merely "intended use" language, which cannot be relied upon to define over the prior art, since Bobo, Jr. as modified, teaches all of the structural limitations of the claims and their recited relationships. The pressure applicator is certainly capable of being used to apply a static pressure as claimed. For example, although Bobo, Jr. discloses using the pressure applicator to measure blood pressure by means of oscillometry, it is noted that during oscillometry, the cuff or bladder is held momentarily once it reaches the maximum applied pressure and the pressure is then decreased stepwise. During each of the stepped deflations and after the maximum pressure is reached, the pressure is constant or static. Alternatively, the bladder is capable of being pressed against the skin manually with a static or constant amount of pressure. Similarly, the pressure applicator is certainly capable of applying a pressure sufficient to partially unload the wall tension of but not to occlude the arteries at the measurement site (see col. 4, lines 25-30 of Bobo, Jr.)

Regarding claim 4, the pressure applicator comprises a fluid chamber an external source of fluid for applying the static pressure to the measurement site (see entire document, especially figs. 1 & 4; col. 4, lines 9-30 of Bobo, Jr.)

Regarding claim 6, the pressure applicator comprises a chamber including a spring therein for applying a static pressure to said measurement site (see entire document, especially col. 3, lines 64-67 of Bobo, Jr.)

Regarding claim 8, the pressure applicator comprises a resilient, elastomeric material (see entire document, especially figs. 1 and 3; col. 5, lines 33-52 of Bobo, Jr.)

Regarding claim 10, the base 19 is of a relatively non-stretchable material (see entire document, especially col. 3, lines 55-60 of Bobo, Jr.), in comparison to a more stretchable material.

Regarding claim 11, the base includes an adhesive layer 22 on its surface facing the pressure applicator and sensor for adhering the base to the subject's skin (see entire document, especially fig. 2; col. 3, lines 59-62 of Bobo, Jr.)

Regarding claims 18 and 20, a data processor system 28 utilizes the measured changes to detect and indicate a medical condition, change in physiological state, and/or systemic blood pressure (see entire document, especially co. 4, lines 18-22 of Bobo, Jr.)

Regarding claim 33, the probe is applied to a measurement site on the subject's skin for measuring changes in the pulsatile blood volume and the measured changes are utilized to detect and indicate a medical condition or change in physiological state (see entire document, especially col. 3, lines 37-67; col. 4, lines 9-30 of Bobo, Jr.)

Regarding claim 37, the probe is applied to a relatively restricted area of the subject's skin on the forehead (see entire document, especially fig. 3 of Bobo, Jr.)

Regarding claim 49, the sensing modality for sensing changes in the pulsatile arterial blood volume at the measurement site is the pressure change within the pressure applicator (see entire document, especially col. 4, lines 9-30 of Bobo, Jr.)

Regarding claim 51, the probe is applied over a skin region predominantly containing microvascular blood vessels for deriving a signal (see entire document, especially fig. 2 of Bobo, Jr.). As to the language "for biofeedback input", the applicants should note that this is merely "intended use" language describing the intended use of the derived signal. This language cannot be relied upon to define over the prior art, since Bobo, Jr., as modified, teaches all of the claimed method steps and their recited relationships. The signal acquired by Bobo, Jr., as modified, is certainly capable of use as a biofeedback input, as claimed.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moses, as applied to claims 1, 3, 4, 10, 18, 20, 21, 33, 38, 50, 52, and 62 above, and further in view of US Patent No. 6,516,289 to David. Moses lacks the probe including an optical sensor for sensing blood oxygen saturation, an electrode for sensing electrical potential, such as the ECG signal of the subject, or an acoustic sensor for sensing a sound signal of the subject. However, David discloses a probe comprising a blood pressure sensor 16, 19 in combination with a blood oxygenation sensor 36, ECG electrode 30, and acoustic sensors 50, 52 (see entire document, especially figs. 2, 4, 6; col. col. 3, lines 16-37; col. 4, lines 1-9 and lines 31-38; col. 5, lines 21-58; col. 6, lines 15-16 of David). All of the claimed component parts are known in the references of

Moses and David. The only difference is the combination of the "old elements" into a single device by incorporation into a single probe. Thus it would have been obvious to one of ordinary skill in the art at the time of invention to combine the ECG electrodes, blood oxygenation sensor, and acoustic sensor of David into the probe of Moses, since the operation of the ECG electrodes, blood oxygenation sensor, and acoustic sensor is in no way dependent upon the operation of the blood pressure sensor, and these sensors can be used in combination for predictable results of providing simultaneous acquisition of important physiological data (see entire document, especially col. 1, lines 50-57 of David), wherein such data is, in particular, useful for the purpose of ambulatory telemedical follow-up of patients in the their own environment and for reciprocal calibration and easy acquisition of important integrated physiological data (see entire document, especially col. 2, lines 4-15 of David).

Claims 23 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moses, as applied to claims 1, 3, 4, 10, 18, 20, 21, 33, 38, 50, 52, and 62 above, and further in view of US Patent No. 3,412,729 to Smith, Jr. Moses lacks the sensor being an optical sensor and the data processor system utilizing the measured changes to produce an oxygen saturation level measurement. Smith, Jr. teaches a probe wherein an optical sensor is used during the application of pressure at the measurement site to obtain a pulse wave signal from which the blood pressure may be determined (see entire document, especially fig. 1; col. 3, line 70-col. 4, line 39;col. 5, line 24-col. 6, line 44 of Smith, Jr.) Therefore, it would have been obvious to one of

ordinary skill in the art to use an optical sensor, such as that of Smith, Jr. in place of the piezoelectric sensor of Moses, as it would merely be the substitution of one known pulse wave and blood pressure sensor for another. Further, it would have been obvious to one of ordinary skill in the art to combine the blood oxygen determination functionality of Smith, Jr. with the probe of Moses, wherein the combination of using an optical probe for both blood pressure and blood oxygenation is shown by Smith, Jr. and such a combination would provide important data in combination with the determination of the well-being of a subject (see entire document, especially col. 1, lines 45-50 of Smith, Jr.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Archibald, as applied to claims above, and further in view of US Patent No. 6,162,181 to Hynson et al. Archibald lacks applying the probe to the palm of the hand or sole of the foot. However, Hynson discloses determining blood pressure by applying a probe on the palm of a user's hand to detect pulsatile arterial blood volume changes in the palmar arch (see entire document, especially col. 2, lines 23-36; co. 4, lines 1-15 of Hynson). Therefore, it would have been obvious to one of ordinary skill in the art a t the time of invention to apply the probe of Archibald to the palm of the hand in order to minimize patient discomfort, acquire stronger oscillations, and minimize finger vasoconstriction problems (see entire document, especially col. 2, lines 41-67 of Hynson) and further because an person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogura in view of Moses, as applied to claims 1, 3, 4, 10, 18, 20, 21, 33, 38, 44, 50, 52, 57, 58, and 62 above, and further in view of David. Ogura, as modified, lacks at least two of the probes including an ECG electrode. However, David describes a blood pressure measuring probe 18 comprising an ECG electrode 30 (see entire document, especially fig. 2, 3; col. 3, lines 16-36 of David). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention combine an ECG electrode with each probe of Ogura, as modified, wherein such a combination is shown by David and would be useful for integration of sensors for the simultaneous acquisition of other important physiological data, for the simultaneous recording, storage, and transmission of data without the need for difficult manipulations, and for reciprocal calibration and easy acquisition of important integrate physiological data (see entire document, especially col. 1, lines 51-57; col. 2, lines 4-11 of David).

Response to Arguments

As to the pending drawing objection, the applicant submitted that the feature is clearly shown in the drawings and refers to the paragraph of p. 10, lines 12-15 and figures 1b and 1c for support. While the identified paragraph states that the surface of base 11 faces the pressure applicator 12 and sensor 13 and the surface includes an adhesive layer 14, none of the figures actually show the adhesive layer "facing" the pressure applicator or the sensor. Instead, the figures show the adhesive layer 14

facing either upwards or downwards, wherein the adhesive layer would have to facing inward in order to be considered "facing" the pressure applicator or sensor. Therefore, the objection to the drawings stand.

Applicant's arguments filed 12/20/07 have been fully considered but they are not persuasive.

As to Bobo, Jr. as modified, the applicants argue that the recitation of "static pressure" is sufficient to distinguish the claimed invention from the prior art. However, the applicant should refer to the "intended use" explanation given under the rejection set forth above and repeated here.

The applicant should note that the language "for applying a static pressure" on lines 6-7 of claim 1 is merely "intended use" language, which cannot be relied upon to define over the prior art, since Bobo, Jr. as modified, teaches all of the structural limitations of the claims and their recited relationships. The pressure applicator is certainly capable of being used to apply a static pressure as claimed. For example, although Bobo, Jr. discloses using the pressure applicator to measure blood pressure by means of oscillometry, it is noted that during oscillometry, the cuff or bladder is held momentarily once it reaches the maximum applied pressure and the pressure is then decreased stepwise. During each of the stepped deflations and after the maximum pressure is reached, the pressure is constant or static. Alternatively, the bladder is capable of being pressed against the skin manually with a static or constant amount of pressure.

The applicant further contends that the force applied by the bladder extending out from the pad and backing when the probe is adhered to the surface but prior to the bladder being pressurized is unknown. Because the force is unknown, the applicant states it would be impossible to ensure that the pressure would impart a static pressure of sufficient magnitude to partially unload the wall tension of, but not to occlude, the arteries as claimed in claim 1. Again, the applicant should be aware that the language "designed to apply to said measurement site, when the base is applied thereto, a static pressure . . ." on lines 11-18 of claim 1 is merely "intended use" language as set forth in the rejection above. Despite the bladder extending out from the pad and backing, the probe is capable of being applied to the skin such that any force imposed by the probe's construction is not sufficient to occlude the artery. Furthermore, Bobo, Jr. discloses the pressure applicator being capable of applying a pressure between 0 and 160 torr (see entire document, especially col. 4, lines 9-30 of Bobo, Jr.) wherein this pressure range extends from a pressure which will not occlude the artery to a pressure which will occlude the artery, and wherein such a range must, therefore, also include a pressure at which the wall tension is partially unloaded but not occluded. Alternatively, such a pressure may be manually applied using the probe. Therefore, the rejection stands.

Applicant's arguments with respect to claims 3, 12-16, 21, 23, 34, 38, 39, 41, 44, 47, 50-52, 57, 58, and 62 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 5, 7, 9, 17, 19, 22, 35, 36, 42, 43, 45, 46, 48, 53-56, 59-61, and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of claim 5, 7, 9, 17, 19, 22, 42, 43, 45, 46, 48, 53-56, 59-61, and 63 was addressed in a previous Office action filed 8/23/07.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 35 and 36, the primary reason for allowance is the inclusion of the probe being applied to arterio-venous shunt rich palmar surfaces of the hand or plantar surfaces of the foot, in combination with all of the other limitations of the claims.

No statement of allowability is being issued for claims 24-32 since they are considered improper multiple dependent claims and have not been further treated on the merits.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/P. C. M./
Examiner, Art Unit 3735